

June 14, 2013

**By Electronic Filing**

Michael E. Gans  
Clerk of the Court  
United States Court of Appeals for the Eighth Circuit  
Thomas F. Eagleton U.S. Courthouse  
111 South 10th Street  
St. Louis, Missouri 63102

Re: United States ex rel. Laurie Simpson v. Bayer Healthcare, et al., No. 12-2979  
Letter Pursuant to Federal Rule of Appellate Procedure 28(j), concerning  
Oral Argument on June 12, 2013

Dear Mr. Gans:

During oral argument I noted that a very recent Statement of Interest, filed after briefing, shows that the federal government would regard it as material to its reimbursement for Baycol prescriptions that, unbeknownst to the government at the time, Bayer had misbranded the drug, 21 U.S.C. § 352(a), 21 C.F.R. § 202.1, rendering it illegal for distribution in interstate commerce, 21 U.S.C. § 331(a)-(c). That Statement of Interest is attached hereto.

In United States ex rel. Krahling v. Merck & Co., No. 10-CV-4374 (E.D. Pa.), asserting a “misbranding” theory (as does Ms. Simpson), the relators alleged that Merck misrepresented the efficacy of its mumps vaccine in violation of federal statutes and agency regulations, including 21 U.S.C. § 352(a), that require Merck to ensure that its mumps vaccine label is not false or misleading. (Ex. 1 ¶¶ 1-4, 117.) On a motion to dismiss, the United States filed a Statement of Interest in support of the relators’ theories of recovery: “The fact that a False Claims Act case may involve omissions to regulatory agencies, discretion in agency action, or violations of regulations does not preclude the action from proceeding.” (Ex. 2 at 3, 7.) The United States further concluded that the case law bears out its position, stating that “courts have allowed relators to litigate False Claims Act suits based on a defendant’s alleged failure to disclose information to a federal agency that, if disclosed, would have affected the Government’s decision to pay money to the defendant.” (Id. at 8.)

Similarly, since briefing, the Department of Justice has announced that it has successfully pursued pharmaceutical companies guilty of misbranding. See Press Release, U.S. Department

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of Justice, ISTA Pharmaceuticals Inc. Pleads Guilty to Federal Felony Charges; Will Pay \$33.5 Million to Resolve Criminal Liability and False Claims Allegations (May 24, 2013) (Ex. 3).

I respectfully submit that, consistent with the points made in our briefs, these recent materials further illustrate the propriety of Ms. Simpson's False Claims Act claims and, in particular, that the DOJ would regard Bayer's alleged misbranding as material to the federal government's reimbursement decisions regarding Baycol.

Respectfully submitted,

/s/ Edward Normand  
Edward Normand

*Attorney for Relator-Appellant*

cc: Adam Hoeflich, Esq. (via ECF)  
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